

REMARKS

The office action rejects claims 14-19, 21-24 and 27-31 under 35 U.S.C. §112, second paragraph as being indefinite. The action notes that there is no antecedent basis in claim 1 for the ion exchange resin as set forth in claims 14-19, 21-24 and 27. Further, the office action rejects claims 14-19, 21-24 and 27-31 as being unpatentable over Eichman (US 5,980,882) in combination with US 5,411,945. Applicants traverse each of these rejections.

The office action notes that claims 1-13, 20, 25-26 are withdrawn from further consideration as being drawn to a nonelected species. Applicants reiterate the traversal to the previous restriction requirement. Further Applicants request reconsideration of claims 1-13, 20, 25-26 in view of the latest amendment filed on October 10, 1992.

Applicants have amended claim 1 to re-present claim 1 as originally filed. Applicants have added claim 32 to re-present the amended claim 1. Applicants believe that these amendments obviate the antecedent basis objections set forth in the office action.

By way of review, the present invention is directed to a fast dissolving orally consumable film containing at least one water soluble polymer, at least one pharmaceutically active agent and at least one taste masking agent.

The Office Action alleges that Eichman discloses a dextromethorphan drug resin complex that can be coated with a film forming material but does not disclose a film forming material such as pullulan. Ozaki is cited for its disclosure of the film forming properties of pullulan. Applicants traverse this rejection and respectfully submit that withdrawal of the rejection is appropriate.

Applicants submit that the combination of Eichman and Ozaki does not suggest the various embodiments of the Applicants' invention. Eichman discloses that drug resin complexes may be formed and then coated with a film forming polymer but Applicants do not coat a drug resin complex with a water soluble polymer. Based on the Examiners' interpretation of Eichman and Ozaki, it would follow that a drug resin complex would be coated with a water soluble polymer, such as pullulan, as disclosed by Ozaki. The various embodiments of the Applicants invention do not do this. Rather, Applicants claim a consumable film adapted to adhere to and dissolve in the mouth, not a drug resin complex coated with a film outer layer.

It is a well settled principle that to establish a *prima facie* case of obviousness of a claimed invention under 35 U.S.C. §103, all the claim limitations must be taught or suggested by the prior art. MPEP 2143.03, *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Applicants submit that the cited references, when taken for the entirety of their teachings, cannot be considered to teach or suggest the Applicants invention. Specifically, a person having ordinary skill in the art would have been motivated by the

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combination of references to make a drug-resin complex coated with a water soluble polymer, such as pullulan. In contrast, the Applicants have made a film that is adapted to adhere to and dissolve in a mouth. Thus, the rejections of the claims based on the combination of the cited references is inappropriate and withdrawal of the rejections and reconsideration is respectfully requested.

Additionally, the teachings of the combined references do not suggest the likelihood of success that a drug/resin will work in a film. Neither Eichman nor Ozaki provides a single specific example by way of illustration of how the invention is to be practiced on any person. The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success when viewed in the light of the prior art. Both the suggestion and the expectation of success must be founded in the prior art, not in the Applicants' disclosure. *In re Dow Chemical Co.* 937 F.2d 469, 5USPZ2d 1529 (Fed. Cir. 1988). Thus, Applicants submit that the teaching of the cited prior art fails to teach or suggest that there would be a reasonable likelihood of success of Applicants' invention.

Accordingly, Applicants respectfully submit that the Application is in condition for allowance and request favorable reconsideration.

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Should the Examiner have any questions or comments concerning the above,
the Examiner is respectfully invited to contact the undersigned attorney at the number
listed below.

Respectfully submitted,


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